TSCA Orders

The suggestion that "unilateral orders" would substantially reduce the length of time it takes to conclude orders raises several concerns. Although there is certainly concern about the amount of detail in proposed consent orders (which submitters must naturally review carefully), the fact is that some consent order terms shift for unknown reasons, contain inappropriate provisions, or substantially change the business case for pursuing a PMN. As a general matter, it *should* take a submitters some time to assess an order and decide whether or not to sign, as it is important to get it right the first time. A unilateral order may allow EPA to conclude an order more quickly, but the substance will not get to market if the terms of the order are overly burdensome. Onerous order terms may be one reason why more PMNs are not subsequently NOC'd (Notice of Commencement, which adds the substance to the Inventory). Unilateral orders would place a significant burden on submitters to press for renegotiation of provisions when the Agency is going down an unnecessary or unreasonable path. Process improvements (including improvements in drafting the orders) would accomplish more to accelerate the process than unilateral orders.

If EPA wants to accelerate closure of consent orders, several approaches might be taken:

- Where EPA finds an order will be required, **require the submitter to provide the first draft,** using the template as a basis, and requiring the submitter to "show its work." By showing its work, the submitter might provide sufficient trade secret information as to ensure confidential treatment/protection against disclosure to support a substantiation requirement.
- Earlier engagement with companies during the order drafting process.
- More consistent consent order terms (ideally aligned with the SNUR conditions at 40 CFR 721), with company visibility to the current internal "boilerplate." Some companies have been told that the "standard" provisions have changed, but how and why is not entirely clear.
- EPA's consent order template hasn't been revised since 9/12/2016 and needs updating: [HYPERLINK "https://protect-us.mimecast.com/s/Saf7CJ67rNuqxyGktzsxEu?domain=epa.gov"]. This template would be more valuable with more annotated instructions making it clear which EPA personnel are accountable for the related content.
- Require an independent quality and consistency review of each proposed order, prior to issuance.
- Redesign the order process, with appropriate consultant support, to be more efficient and accountable in its use of public resources and time. This would take more time, of course, and in the meantime there are steps that can be taken without such a review.

Typical concerns

- Proposed consent orders have contained inappropriate conditions due to mistakes in the risk assessment or just plain typos that needed to be corrected. The original drafts of consent orders could do a better job of expressing and addressing the conditions sought by the PMN submitter, in light of the true risks posed by the substance. Too often, the consent order signed and delivered to the submitter is a work product that barely reflects, or doesn't reflect, the PMN submitted and subsequent dialogue between the submitter and the case manager.

- Despite provisions allowing modification of an existing consent order, efforts to modify orders are generally not successful. There seems to be little that compels or incentivizes EPA to discuss modifications. Given the many other priorities at the Agency, consent order modifications easily drop in priority.
- Early engagement on potential order provisions. If a submitter knows earlier in the process that there are particular concerns, or if there was an opportunity to review a draft order before EPA management sign off, a mutually acceptable resolution could likely be negotiated much sooner. This is not a question of communication by case managers, but the fact that EPA's process requires orders to get to an advanced stage before the submitter has a chance to review and identify concerns with the proposed order.
- One challenge is EPA's lack of understanding of supply chain and industrial customer business interactions. Any proposed order provisions that restrict downstream use and communications add complexity and it takes time to get everyone aligned.
- In general, the perception that industry takes too long to respond to a proposed order (and the ensuing perception that the submitter doesn't care about commercializing a product) is not true. Most companies are not sitting on consent orders. The additions and unique limitations and considerations relative to each chemical substance makes it challenging to digest and share within a business – and with customers.
- What EPA may consider to be a "simple" limitation is at times enough to kill a business effort. As a result, many background considerations, adaptations and the like have to be completed before responding to EPA. Then the process starts over as the agency now considers a new perspective. And that process can continue, of course.
- There are also concerns about the lack of response by parties outside the case manager's control. Risk evaluators and support teams in EPA don't answer to the case manager which often makes it difficult to get things to move forward in the timely manner. Weeks and even months delay within the agency for a simple response are experienced frequently.

Examples

- Case manager indicated that EPA has aquatic toxicity concerns for a new substance and intended to include a "release to water" provision with a concentration threshold. The intended use does not have any anticipated releases to water, so based on the boilerplate order language on EPA's website ([HYPERLINK "https://protect-us.mimecast.com/s/i4QQCL95wvHRLRwEFBnKfh?domain=epa.gov"]), the company would be willing to accept the condition. When the draft order was received, hazard communication conditions had been added and the "release to water" section had been expanded to include a reporting requirement: *"If for any reason the Company fails to comply with the strict release limitations applicable to the PMN substance under this "Release to Water" section, the Company shall notify EPA within 5 days of the release..."*
- Apparent changes in "boilerplate" language. Some new orders require the submitter to obtain a written agreement from every customer that they will abide by the same conditions. This approach has a significant potential impact on customer acceptance of a new product. It's one thing to notify customers to use and dispose of the product properly; it's quite another to require customers to agree in writing to immediately inform

EPA if they *ever* fail to do so. This is not part of the publicly available boilerplate language at the link above.

- EPA uncertainty about (or EPA not being prepared to address) how provisions such as the customer agreement provisions are affected by the TSCA Audit Policy and how a SNUR might address the requirements. By the time the draft order has been sent to the submitter, EPA generally contends that the order has been through EPA management review and sign-off, and staff seem reluctant to go through the process again. This is an example where a submitter would be unwilling to sign the order until there is some resolution.
- Requests to submit alternative tests are not addressed in a timely way. Some submitters request alternative tests relative to OECD-approved methods. These are typically nothing new or different, simply requests to align methodologies (particularly since the EU is no longer accepting certain toxicity tests, preferring to use others). These would appear to be simple yes/no questions on whether the alternative test will satisfy the Agency's concern. Some of these questions go unanswered for months (several examples of waiting on answers for more than 3 months).
- There are examples where the "engineering report" for the PMN – meaning the exposure assessment to be used in the risk assessment – doesn't address the input received. The submitter may have submitted voluminous health and safety data with the PMN and spent time going through it with the case manager – none of which is considered in the engineering report. Subsequently, the engineering report generates an assessment based on standard EPA assumptions that bear no semblance to the information submitted by, or expectations of, the submitter. The result of that assessment is used to draft an original consent order sent to the submitter, pre-signed by EPA, with a cover letter insisting that the submitter sign the order within 30 days or withdraw the PMN. The submitter then has the choice of trying to fix the critical stuff as best it can and live with a barely acceptable outcome; or having the PMN withdrawn and losing all that time. This suggests a longer standing structural or management problem in the order process.
- Orders are of course unique to specific substances, but there are three areas in particular where additional EPA experience and expertise could reduce the need for order provisions requiring modification:
- **Testing costs**:
    - EPA could be more judicious in identifying mandatory "targeted testing" indexed to aggregate production quantities, time, or some other variable; and that it make greater use of read-across. If a single party receives a unilateral order requiring a 2-year cancer study as part of targeted testing, that order completely rewrites the business case.
    - The value of an order often comes down to whether the benefits of the competitive edge from being first in market, or in simply opening the domestic market to the new chemistry, outweigh the costs of compliance, including any targeted testing imposed by the order in addition to the sunk PMN-related testing costs.
    - Testing costs could be spread more equitably by using 721.80(r) or (u) to impose a targeted testing requirements on those following the PMN submitter into the US market who, presumably, would comply with their SNUR by sharing the targeted testing cost with the original submitter.

- **Manufacturing controls**:
  - Requiring that a facility comply with air pollution controls imposed separately under both TSCA and the CAA, practically speaking, is too complicated.
  - EPA should tie any air emission controls needed to support its statutory TSCA Section 5 finding, whatever it may be, to a mandatory Clean Air Act requirement, typically one administered by the State (or, if not the State, then by regional EPA).
- **Hazard Communication**:
  - Consider the Hazard Communication section of every consent order.
  - Industry continues to hear from case managers that the EPA staff does not have expertise to discuss Globally Harmonized System for Classification and Labeling (GHS) or GHS-like Hazard Communication issues. This is somewhat surprising in 2019, as OSHA's program has been in place since March 2012 and became mandatory in March 2015.
  - GHS-related hazard communication disputes often arise and result in compromises that can add to the ambiguity/uncertainty in orders.
  - The resulting order can have industry creating SDSs and labels that, by including ambiguous and internally inconsistent statements, may violate OSHA's GHS regulation.
  - EPA could remedy this concern, in part, by finalizing its July 28, 2016 proposed rule offering to harmonize its SNUR regulations to OSHA's GHS regulation. See [HYPERLINK "https://protect-us.mimecast.com/s/VdDRCER6m0u3BnrwiN0JgE?domain=regulations.gov"] and [HYPERLINK "https://protect-us.mimecast.com/s/9VmcCG6QoMu1wqxrf7RLsx?domain=regulations.gov"]